Theodore V. H. Mayer Vilia B. Hayes Robb W. Patryk HUGHES HUBBARD & REED LLP One Battery Park Plaza New York, NY 10004-1482 (212) 837-6000

Attorneys for Defendant Merck & Co., Inc.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

ANDERSON, MARGARET, et vir, ANDERSON, IOHN, CAMPBELL, JOHN, et ux, CAMPBELL, ELIZABETH, COLLINS, MARION, HAMILTON, WILLIAM, et ux, HAMILTON, JANETTE, REID, HENRY, et ux, REID, CAROLYN, WILLIAMSON, JOHN, et ux, WILLIAMSON, MARGARET,

Plaintiffs,

-against-

MERCK & CO., INC., and MERCK SHARP & DOHME, LTD.,

Defendants.

No.: 07 Cw 10514

ANSWER AND JURY DEMAND OF DEFENDANT MERCK & CO., INC.

Defendant Merck & Co., Inc. ("Merck") answers the Complaint ("Complaint") herein as follows:

Denies each and every allegation contained in the Introductory paragraph of the Complaint except admits that Plaintiffs purport to bring an action for damages but denies that there is any legal or factual basis for relief. Merck further admits that it is a New Jersey Corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey and is authorized to do business in the State of New York.

#### **RESPONSE TO "PARTIES"**

- 1. Denies each and every allegation contained in paragraph 1 of the Complaint.
- 2. Denies each and every allegation contained in paragraph 2 of the Complaint.
- 3. Denies each and every allegation contained in paragraph 3 of the Complaint except admits that Merck is a New Jersey Corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.
- 4. Denies each and every allegation contained in paragraph 4 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.
- 5. Denies each and every allegation contained in paragraph 5 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004, and that Vioxx was registered, marketed and sold in approximately 80 countries outside the United States.
- 6. Denies each and every allegation contained in paragraph 6 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.
- 7. Denies each and every allegation contained in paragraph 7 of the Complaint except admits that Merck marketed the prescription medicine Vioxx.
- 8. Denies each and every allegation contained in paragraph 8 of the Complaint except admits that Merck marketed the prescription medicine Vioxx.

- 9. Merck denies each and every allegation contained in paragraph 9 of the Complaint, except admits that Merck marketed and distributed Vioxx until it voluntarily withdrew Vioxx from the worldwide market on September 30, 2004, and that Vioxx was registered, marketed and sold in approximately 80 countries outside the United States, including the United Kingdom and Ireland. Merck further avers that worldwide Vioxx sales figures exceeded \$2 billion in the years 2000, 2001, 2002 and 2003, and that worldwide sales of Vioxx for the first six months of 2004 were \$1.3 billion.
  - Denies each and every allegation contained in paragraph 10 of the Complaint.
     RESPONSE TO "FACTS COMMON TO ALL COUNTS"
- 11. Denies each and every allegation contained in paragraph 11 of the Complaint except admits that Vioxx is the brand name for rofecoxib and that Vioxx reduces pain and inflammation and the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2).
- 12. Denies each and every allegation contained in paragraph 12 of the Complaint except admits that Vioxx reduces pain and inflammation and the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2)
- 13. Denies each and every allegation in paragraph 13 of the Complaint except admits that Merck submitted a New Drug Application for Vioxx on November 23, 1998 and respectfully refers the Court to the referenced New Drug Application for its actual language and full text.

- 14. Denies each and every allegation in paragraph 14 of the Complaint except admits that Merck submitted a New Drug Application for Vioxx on November 23, 1998 and respectfully refers the Court to the referenced New Drug Application for its actual language and full text.
- 15. Denies each and every allegation contained in paragraph 15 of the Complaint except admits that in May 1999 Merck received FDA approval to manufacture and market the prescription medicine Vioxx as safe and effective for certain indicated uses in a manner consistent with the information contained in the United States Food and Drug Administration ("FDA")-approved prescribing information and respectfully refers the Court to the relevant prescribing information for its actual language and full text.
- 16. Denies each and every allegation set forth in paragraph 16 of the Complaint and respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its actual language and full text.
- 17. Denies each and every allegation set forth in paragraph 17 of the Complaint and respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its actual language and full text.
- Denies each and every allegation contained in paragraph 18 of the Complaint 18. and avers that in March 2000 Merck forwarded to the FDA the Vioxx Gastrointestinal Outcomes Research (VIGOR) study and subsequently, in June 2000, filed a supplemental New Drug Application (sNDA) that included the VIGOR study. Merck respectfully refers the Court to the referenced sNDA for its actual language and full text.
- 19. Denies each and every allegation in paragraph 19 of the Complaint except admits that the referenced study exists and avers that a primary objective of the VIGOR

study was to assess whether Vioxx would be associated with a lower incidence of confirmed, clinically important upper gastrointestinal events than naproxen. Merck respectfully refers the Court to the referenced study for its actual language and full text.

- 20. Denies each and every allegation contained in paragraph 20 of the Complaint except admits that the referenced study exists and respectfully refers the Court to said study for its actual language and full text. Merck further admits that it is currently a member of the European League Against Rheumatism ("EULAR") and that it has been a sponsor of EULAR since 1999.
  - Denies each and every allegation contained in paragraph 21 of the Complaint. 21.
- 22. Denies each and every allegation contained in paragraph 22 of the Complaint except admits that the referenced publication exists and respectfully refers the Court to said publication for its actual language and full text.
- 23. Denies each and every allegation contained in paragraph 23 of the Complaint except admits the existence of the journal, the article contained therein and respectfully refers the Court to the referenced article for its actual language and full text.
- 24. Denies each and every allegation contained in paragraph 24 of the Complaint except admits the referenced articles exist and respectfully refers the Court to the referenced articles for their actual language and full text.
- 25. Denies each and every allegation in paragraph 25 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

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- 26. Denies each and every allegation in paragraph 26 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.
- 27. Denies each and every allegation in paragraph 27 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.
- 28. Denies each and every allegation contained in paragraph 28 of the Complaint except admits that in April 2002 the FDA approved certain changes to the Vioxx prescribing information and respectfully refers the Court to the relevant prescribing information for Vioxx for its actual language and full text and admits that the FDA approved a so-called "Dear Doctor" letter and respectfully refers the Court to the referenced letter for its actual language and full text.
- 29. Denies each and every allegation in paragraph 29 of the Complaint except Merck admits that in April 2002 the FDA approved certain changes to the Vioxx prescribing information and respectfully refers the Court to the relevant prescribing information for Vioxx for its actual language and full text.
- 30. Denies each and every allegation contained in paragraph 30 of the Complaint except admits that the FDA approved a so-called "Dear Doctor" letter and respectfully refers the Court to the referenced letter for its actual language and full text.
  - 31. Denies each and every allegation contained in paragraph 31 of the Complaint.
- 32. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 32 of the Complaint.
  - 33. Denies each and every allegation contained in paragraph 33 of the Complaint.

- 34. Denies each and every allegation contained in paragraph 34 of the Complaint except admits that Plaintiffs purport to quote from one of Merck's Annual Reports and respectfully refers the Court to said Annual Report for its actual language and full text.
- 35. Denies each and every allegation contained in paragraph 35 of the Complaint except admits that Plaintiffs purport to quote from one of Merck's SEC filings and respectfully refers the Court to said filing for its actual language and full text.
- 36. Denies each and every allegation contained in paragraph 36 of the Complaint, except admits the referenced article exists, and respectfully refers the Court to said article for its actual language and full text.
  - 37. Denies each and every allegation contained in paragraph 37 of the Complaint.
- 38. Denies each and every allegation contained in paragraph 38 of the Complaint except admits that the VIGOR study involving Vioxx exists and that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001, and respectfully refers the Court to the referenced letter and study for their actual language and full text.
- 39. Denies each and every allegation contained in the first, second, third, fourth and fifth sentences of paragraph 39 of the Complaint, except admits that on September 23, 2004, Merck was informed that the External Safety Monitoring Board (ESMB) had recommended that the APPROVe study be stopped when preliminary results showed a small increased risk of confirmed cardiovascular events beginning after 18 months of continuous treatment with Vioxx. Denies each and every allegation contained in the sixth sentence of paragraph 39 of the Complaint except admits that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after

18 months of treatment in the patients taking Vioxx compared with those taking placebo.

Merck further avers that given the availability of alternative therapies and questions
raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx
from the worldwide market best served the interests of patients.

40. Denies each and every allegation contained in paragraph 40 of the Complaint.

## RESPONSE TO "COUNT I PRODUCTS LIABILITY – DEFECTIVE DESIGN"

- 41. With respect to the allegations contained in paragraph 41 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 40 of this Answer with the same force and effect as though set forth here in full.
- 42. Denies each and every allegation contained in paragraph 42 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.
  - 43. Denies each and every allegation contained in paragraph 43 of the Complaint.
- 44. Denies each and every allegation contained in the first and third sentences of paragraph 44 of the Complaint, except admits that the active ingredient rofecoxib was marketed under the brand name Vioxx in the United Kingdom. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the second sentence of paragraph 44 of the Complaint.
- 45. Denies each and every allegation contained in the first, second and fourth sentences of paragraph 45 of the Complaint, and respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its actual language and full

text. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the third sentence of paragraph 45 of the Complaint.

- 46. Denies each and every allegation contained in paragraph 46 of the Complaint.
- 47. Denies each and every allegation contained in paragraph 47 of the Complaint.
- 48. Denies each and every allegation contained in paragraph 48 of the Complaint.

# RESPONSE TO "COUNT II PRODUCTS LIABILITY – FAILURE TO WARN"

- 49. With respect to the allegations contained in paragraph 49 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 48 of this Answer with the same force and effect as though set forth here in full.
- 50. The allegations contained in paragraph 50 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.
  - 51. Denies each and every allegation contained in paragraph 51 of the Complaint.
  - 52. Denies each and every allegation contained in paragraph 52 of the Complaint.
  - 53. Denies each and every allegation contained in paragraph 53 of the Complaint.
- 54. Denies each and every allegation contained in paragraph 54 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.
  - 55. Denies each and every allegation contained in paragraph 55 of the Complaint.

#### RESPONSE TO "COUNT III NEW JERSEY CONSUMER FRAUD ACT"

- 56. With respect to the allegations contained in paragraph 56 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 55 of this Answer with the same force and effect as though set forth here in full.
- 57. The allegations contained in the first sentence of paragraph 57 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said sentence and respectfully refers the Court to the referenced statute for its actual language and full text. Denies each and every allegation contained in the second sentence of paragraph 57 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.
  - 58. Denies each and every allegation contained in paragraph 58 of the Complaint.
  - 59. Denies each and every allegation contained in paragraph 59 of the Complaint.
  - 60. Denies each and every allegation contained in paragraph 60 of the Complaint.
  - 61. Denies each and every allegation contained in paragraph 61 of the Complaint.
  - 62. Denies each and every allegation contained in paragraph 62 of the Complaint.
- 63. The allegations contained in paragraph 63 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.
  - 64. Denies each and every allegation contained in paragraph 64 of the Complaint.

- 65. Denies each and every allegation contained in paragraph 65 of the Complaint.
- 66. Denies each and every allegation contained in paragraph 66 of the Complaint.
- 67. Denies each and every allegation contained in paragraph 67 of the Complaint.
- 68. Denies each and every allegation contained in paragraph 68 of the Complaint.
- 69. The allegations contained in paragraph 69 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.
  - 70. Denies each and every allegation contained in paragraph 70 of the Complaint.
  - 71. Denies each and every allegation contained in paragraph 71 of the Complaint.

# RESPONSE TO "COUNT IV BREACH OF EXPRESS WARRANTY"

- 72. With respect to the allegations contained in paragraph 72 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 71 of this Answer with the same force and effect as though set forth here in full.
  - 73. Denies each and every allegation contained in paragraph 73 of the Complaint.
- 74. The allegations contained in paragraph 74 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph, including subparagraphs a) through c).
  - 75. Denies each and every allegation contained in paragraph 75 of the Complaint.
  - 76. Denies each and every allegation contained in paragraph 76 of the Complaint.

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- 77. The allegations contained in the first sentence of paragraph 77 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said sentence.

  Denies each and every allegation contained in the second sentence of paragraph 77 of the Complaint.
- 78. The allegations contained in 78 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.
  - 79. Denies each and every allegation contained in paragraph 79 of the Complaint.
  - 80. Denies each and every allegation contained in paragraph 80 of the Complaint.

#### RESPONSE TO "COUNT VI VIOLATION OF GENERAL BUSINESS LAW § 349"

- 81. With respect to the allegations contained in paragraph 81 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 80 of this Answer with the same force and effect as though set forth here in full.
- 82. The allegations contained in 82 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.
- 83. The allegations contained in 83 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck

denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.

- 84. The allegations contained in 84 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.
- 85. Denies each and every allegation contained in paragraph 85 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx until it voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.
  - 86. Denies each and every allegation contained in paragraph 86 of the Complaint.
  - 87. Denies each and every allegation contained in paragraph 87 of the Complaint.
  - 88. Denies each and every allegation contained in paragraph 88 of the Complaint.
  - 89. Denies each and every allegation contained in paragraph 89 of the Complaint.
  - 90. Denies each and every allegation contained in paragraph 90 of the Complaint.
  - 91. Denies each and every allegation contained in paragraph 91 of the Complaint.
  - 92. Denies each and every allegation contained in paragraph 92 of the Complaint.
- 93. The allegations contained in 93 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.
  - 94. Denies each and every allegation contained in paragraph 94 of the Complaint.
  - 95. Denies each and every allegation contained in paragraph 95 of the Complaint.

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- 96. Denies each and every allegation contained in paragraph 96 of the Complaint.
- 97. Denies each and every allegation contained in paragraph 97 of the Complaint.

## RESPONSE TO "COUNT VI LOSS OF CONSORTIUM"

- 98. With respect to the allegations contained in paragraph 98 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 97 of this Answer with the same force and effect as though set forth here in full.
  - 99. Denies each and every allegation contained in paragraph 99 of the Complaint.
  - 100. Denies each and every allegation contained in paragraph 100 of the Complaint.

#### RESPONSE TO "CONCLUSION"

101. Plaintiffs' "Conclusion" section of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation in the "Conclusion" section of Plaintiffs' Complaint, including subparagraphs A through F, and denies that Plaintiffs are entitled to the relief requested.

## AS FOR A FIRST DEFENSE, MERCK ALLEGES:

102. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and statutes of repose and is otherwise untimely.

## AS FOR A SECOND DEFENSE, MERCK ALLEGES:

103. The Complaint fails to state a claim upon which relief can be granted.

### AS FOR A THIRD DEFENSE, MERCK ALLEGES:

104. The claims of the Plaintiffs may be barred, in whole or in part, from recovery because they have made statements or taken actions that preclude them from asserting claims or constitute a waiver of their claims.

## AS FOR A FOURTH DEFENSE, MERCK ALLEGES:

105. The claims of the Plaintiffs may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.

### AS FOR A FIFTH DEFENSE, MERCK ALLEGES:

106. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

## AS FOR A SIXTH DEFENSE, MERCK ALLEGES:

107. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were cause in whole or in part through the operation of nature or other intervening cause or causes.

## AS FOR A SEVENTH DEFENSE, MERCK ALLEGES:

108. To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

## AS FOR AN EIGHTH DEFENSE, MERCK ALLEGES:

109. To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of Vioxx,

such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

### AS FOR A NINTH DEFENSE, MERCK ALLEGES:

110. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

## AS FOR A TENTH DEFENSE, MERCK ALLEGES:

111. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

## AS FOR AN ELEVENTH DEFENSE, MERCK ALLEGES:

112. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Vioxx.

## AS FOR A TWELFTH DEFENSE, MERCK ALLEGES:

113. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

#### AS FOR A THIRTEENTH **DEFENSE, MERCK ALLEGES:**

114. To the extent Plaintiffs settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

#### AS FOR A FOURTEENTH **DEFENSE, MERCK ALLEGES:**

115. To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

#### AS FOR A FIFTEENTH **DEFENSE, MERCK ALLEGES:**

116. Plaintiffs' claims of fraud are barred by reason of Plaintiffs' failure to allege the circumstances constituting fraud with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure.

#### AS FOR A SIXTEENTH **DEFENSE, MERCK ALLEGES:**

Plaintiffs' claims are barred, in whole or in part, under the applicable state law 117. because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

#### AS FOR A SEVENTEENTH **DEFENSE, MERCK ALLEGES:**

118. Plaintiffs' claims are barred in whole or in part by the First Amendment.

#### AS FOR A EIGHTEENTH **DEFENSE, MERCK ALLEGES:**

Plaintiffs' claims are barred in whole or in part because the product at issue was 119. made in accordance with the state of the art at the time it was manufactured.

#### AS FOR A NINETEENTH **DEFENSE, MERCK ALLEGES:**

120. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

#### AS FOR A TWENTIETH **DEFENSE, MERCK ALLEGES:**

121. This case is more appropriately brought in a different venue.

#### AS FOR A TWENTY-FIRST **DEFENSE, MERCK ALLEGES:**

122. The claims of Plaintiffs may be barred, in whole or in part, from recovery because, in this or other courts, they have brought actions and have received judgments on parts of some or all claims asserted herein.

#### AS FOR A TWENTY-SECOND **DEFENSE, MERCK ALLEGES:**

123. The claims of Plaintiffs may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

#### AS FOR A TWENTY-THIRD **DEFENSE, MERCK ALLEGES:**

124. The claims of Plaintiffs may be barred, in whole or in part, from recovery by release as to their claims.

#### AS FOR A TWENTY-FOURTH **DEFENSE, MERCK ALLEGES:**

The claims of Plaintiffs may be barred, in whole and in part, by the doctrine of 125. laches.

#### AS FOR A TWENTY-FIFTH **DEFENSE, MERCK ALLEGES:**

126. The claims of Plaintiffs are barred, in whole or in part, by their failure to mitigate damages.

#### AS FOR A TWENTY-SIXTH **DEFENSE, MERCK ALLEGES:**

127. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

#### AS FOR A TWENTY-SEVENTH **DEFENSE, MERCK ALLEGES:**

128. The claims of Plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence.

#### AS FOR A TWENTY-EIGHTH **DEFENSE, MERCK ALLEGES:**

The claims of Plaintiffs may be barred, in whole or in part, by the governing 129. state laws.

#### AS FOR A TWENTY-NINTH **DEFENSE, MERCK ALLEGES:**

130. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

#### AS FOR A THIRTIETH **DEFENSE, MERCK ALLEGES:**

131. Plaintiffs have not sustained any injury or damages compensable at law.

### AS FOR A THIRTY-FIRST DEFENSE, MERCK ALLEGES:

132. To the extent that Plaintiffs seek exemplary or punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

## AS FOR A THIRTY-SECOND DEFENSE, MERCK ALLEGES:

133. To the extent that Plaintiffs seek exemplary or punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of exemplary or punitive damages is barred.

### AS FOR A THIRTY-THIRD DEFENSE, MERCK ALLEGES:

134. Plaintiffs' demand for exemplary or punitive damages is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

## AS FOR A THIRTY-FOURTH DEFENSE, MERCK ALLEGES:

135. Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

## AS FOR A THIRTY-FIFTH DEFENSE, MERCK ALLEGES:

136. Plaintiffs' claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation Plaintiffs allege to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

#### AS FOR A THIRTY-SIXTH **DEFENSE, MERCK ALLEGES:**

137. Plaintiffs' claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

#### AS FOR A THIRTY-SEVENTH **DEFENSE, MERCK ALLEGES:**

138. Plaintiffs' claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

#### AS FOR A THIRTY-EIGHTH **DEFENSE, MERCK ALLEGES:**

Plaintiffs' claims are barred by the doctrine of contributory negligence. 139.

#### AS FOR A THIRTY-NINTH **DEFENSE, MERCK ALLEGES:**

140. Plaintiffs' claims under New York General Business Law Section 349 are barred by reason of Plaintiffs' failure to allege sufficient facts identifying any statement or misrepresentation alleged to constitute a deceptive act or practice and their failure to plead causation with sufficient specificity.

#### AS FOR A FORTIETH **DEFENSE, MERCK ALLEGES:**

To the extent Plaintiffs' claims under New York General Business Law Section 141. 349 are based on conduct that took place outside the state of New York, the claims are barred.

#### AS FOR A FORTY-FIRST **DEFENSE**, MERCK ALLEGES:

142. Merck's conduct and all activities with respect to the subject product were fair and truthful based upon the knowledge existing at the relevant time alleged in the

Complaint. Therefore, Plaintiffs' claims under New York Business Corporation Law § 349 are barred.

## AS FOR A FORTY-SECOND DEFENSE, MERCK ALLEGES:

143. Any injuries, losses or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the failure of Plaintiffs to exercise ordinary care and to follow the advice, information, warnings and/or instructions provided with the subject pharmaceutical product and therefore Plaintiffs' recovery, if any, must be diminished by the proportion of the negligence of Plaintiffs which proximately caused or contributed to the alleged injuries, losses or damages.

### AS FOR A FORTY-THIRD DEFENSE, MERCK ALLEGES:

144. Plaintiffs' claims are barred in whole or in part because the product at issue was not defective at the time that it left Merck's control.

## AS FOR A FORTY-FOURTH DEFENSE, MERCK ALLEGES:

145. This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

## AS FOR A FORTY-FIFTH DEFENSE, MERCK ALLEGES:

146. Plaintiffs' claims are barred in whole or in part because Plaintiffs assert their claims under laws that do not have extra-territorial application to Merck or to its activities as alleged by Plaintiffs.

### AS FOR A FORTY-SIXTH DEFENSE, MERCK ALLEGES:

147. There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiffs.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

### **JURY DEMAND**

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York

November **20**, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

Theodore V. H. Mayer

Vilia B. Hayes Robb W. Patryk

One Battery Park Plaza New York, New York 10004-1482 (212) 837-6000

Attorneys for Defendant Merck & Co., Inc.

#### **CERTIFICATE OF SERVICE**

I hereby certify that on this 21<sup>st</sup> day of November 2007, I caused a copy of the foregoing ANSWER AND JURY DEMAND OF DEFENDANT MERCK & CO., INC., and NOTICE OF REMOVAL OF DEFENDANT MERCK & CO., INC., to be served via first-class mail, postage prepaid, on the following:

NEWMAN FITCH ALTHEIM MYERS, P.C. Charles D. Cole, Jr., Esq. 14 Wall Street New York, New York 10005

Joseph C. Blanks, Esq. Post Office Drawer 999 Doucette, Texas 75942

The above addresses has appeared on the prior papers in this action as the office addresses of the attorneys for Plaintiffs.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on November 21, 2007